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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,221	11/17/2003	Jonathan J. Langberg	PVI-5813CP1CN1	5022
30452 7590 07/08/2010 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614				
EXAMINER STEWART, JASON-DENNIS NEILKEN				
ART UNIT		PAPER NUMBER		
3738				
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07/08/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,221

Applicant(s)

LANGBERG ET AL.

Examiner

JASON-DENNIS STEWART

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 31-34, 36-38, 40, 42, 44-46, 50-68 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 25, 35, 39, 41 and 43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62-68 is/are allowed.
- 6) ☒ Claim(s) 24, 31-34, 36-38, 40, 42, 44-46, 50-61, and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-840)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 29 January 2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The following is a Final Office action in response to communications received on 10/15/2008. Claims 24, 54, and 70 have been amended. Therefore, Claims 24, 31-34, 36-38, 40, 42, 44-46, 50-68, and 70 are currently pending and addressed below.

Allowable Subject Matter

1. Claim 62-68 are allowed.
2. The following is a statement of reasons for the indication of allowable subject matter: The prior art, alone or in combination, does not disclose an elongate element which carries a cardiac pacing electrode, with a first and second shape that, when implanted in the coronary sinus in the second shape, the elongate body has a best fit curve of constant radius within a range of from about 1.0 cm to about 2.0 cm.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24, 31-33, 37, 38, 40, 42, 46, 50, 54-57, 59, 60, 61, and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Morris et al. 6,321,123.
5. Morris discloses an elongate body **10**, a forming element **42**, a cardiac pacing electrode **22** wherein the electrode is fully capable of remaining with the elongate body after the elongate body is manipulated, the elongate body is in the coronary sinus, and the portion of the forming element is removed from the coronary sinus (col. 3, ll. 37- 66). Morris also discloses an anchor 16 for keeping the elongate body in position within the vessel. The elongate body as well as the cardiac pacing electrode are able to be manipulated by the forming body from a first to a second shape. Also, Morris discloses that the elongate body can be expanded against the walls of the coronary sinus. The elongate body therefore is fully capable of exerting a force on the wall. *It should be noted that "a therapeutically effective amount" does not denote any specific amount or reduction in regurgitation, nor does it suggest any amount of force required to perform the action. It is seen by the Examiner as a functional limitation that carries limited patentable weight in the absence of differentiating structure.* Also, the location of implantation of the device in the claims is seen as functional language by the Examiner and holds no patentable weight in the absence of differentiating structure.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. 6,321,123.

8. Morris discloses the invention as claimed and as discussed above. However, Morris does not positively disclose the claimed ranges in Claims 44 and 45 for the length and cross-section respectively. It has been held "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, See MPEP 2144.05, Part II, Section A.

9. Claims 34-36, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. '123 in view of Li et al. (5,879,295).

10. Morris discloses the invention as claimed and as discussed above. However, Morris, while implied, Morris does not positively disclose a movable lock.

Li discloses a movable lock (col. 4, ll. 58-66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Morris in order to lock an electrode-catheter in position as taught by Li such that the apparatus remains in the desired position and the surgeon can then proceed to place the device there.

11. Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. 6,321,123 in view of Thompson et al. 6,048,329.

12. Morris discloses the invention as claimed and as discussed above. However, Morris does not positively disclose a formable element made of a NiTi alloy.

Morris discloses a NITINOL® forming element (col. 6, ll. 1-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Morris and use the material disclosed in Thompson in order to create a flexible support structure as disclosed by Thompson since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

13. Applicant's arguments filed 01/29/10 have been fully considered but they are not persuasive. The Applicant argues that Morris does not teach a device capable of exerting a force on the coronary sinus wall that is "sufficient to reduce mitral valve regurgitation by a therapeutically effective amount". The Examiner respectfully disagrees. As noted above, it should be noted that "a therapeutically effective amount" does not denote any specific amount or reduction in regurgitation, nor does it suggest any amount of force required to perform the action. It is seen by the Examiner as a functional limitation that carries limited patentable weight in the absence of differentiating structure.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JASON-DENNIS STEWART** whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner, Art Unit 3774

/Jason-Dennis Stewart/
Examiner, Art Unit 3738